REISSUE APPLICATION S/N 09/241,825

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Mark Lyte

Serial No.:

09/241,825 Filed: February 1, 1999

Title:

SEP 0 5 2000

Examiner: H. Lilling

Group Art Unit: 1651

Docket: 933.001USR

COMPOUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

APPEAL BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES OF THE UNITED STATES PATENT AND TRADEMARK OFFICE RECEIVED

SEP 0 8 2000

TECH CENTER 1600/2000

Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

This is an appeal from the Office Action (Advisory Action) mailed on July 14, 2000 and the Office Action (Final Rejection) mailed March 24, 2000, finally rejecting claims 23-42. Claims 1-2, the original claims in the Patent from which this Reissue was filed, are still allowed.

This Brief is being filed in triplicate along with a check for \$155.00 to cover the fee for the appeal. Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

09/05/2000 YPOLITE1 00000046 09241825

01 70:220

150.00 OP

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

### **TABLE OF CONTENTS**

RECEIVED

SEP 0 8 2000
Page No.
FECH CENTER 1800/2000

Real Party in Interest	3
Status of Claims.	4
Status of Amendments	5
Summary of the Invention.	6
Issues	7
Related Appeals and Interferences	8
Grouping of Claims	9
Arguments	10-32
Annendix	33-35

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

### **REAL PARTY IN INTEREST**

The Application that forms the substance of this appeal is assigned to Bionutrix, Inc. A small party corporation incorporated under the laws of the State of Minnesota, having a place of business at 1150 Hennepin Avenue South, Suite 1103, Minneapolis, MN 55403.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

### **STATUS OF CLAIMS**

Claims 1-2 have been allowed, those claims being the original claims allowed in U.S. Patent No. 5,629,349. 40.

Claims 23-42, all of the remaining claims in the Application for Reissue have been rejected under various Non-statutory grounds.

No claims have been rejected under 35 USC102 or 35 USC 103.

No other claims are pending in the application. No other rejections remain in the Application.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

### **STATUS OF AMENDMENTS**

A Request for Reconsideration without any amendments to the claims was filed after the final rejection under 37 C.F.R. 1.116, and no substantive objection to claims amended or submitted during prosecution that have not been overcome were made.

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

#### **SUMMARY OF THE INVENTION**

A method is described for modulating the proliferation of micro-organisms in the introduction of neurochemicals (including certain hormones such as catecholamines) into an *in vitro* culture of the bacteria, viruses or the like. (Column 1, lines 21-25). The addition of these neurochemicals to cultures can cause vast increases in the bacterial growth capacity. (Column 3, lines 47-52). In certain circumstances with specific classes of bacteria, growth rates are suppressed. (Column 3, lines 52-57). The tremendous increases in rates of proliferation provides a significant potential advantage in the ability to harvest by-products from the growth of bacteria. (Column 12, lines 40-63).

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

#### **ISSUES ON APPEAL**

The generic issue in this Appeal is whether the subject matter of claims 23-42 was abandoned or otherwise lost to Applicant by the issuance of U.S. Patent No. 5,629,349. The generic question is whether a Reissue Application, under the facts of the prosecution of U.S. Patent No. 5,629,349, is the appropriate vehicle for redressing errors and mistakes in the prosecution of that Patent. The specific questions raised in the Office Actions and rejections are whether Applicant has lost rights and now suffers an inability to prosecute claims in a Reissue Patent Application. The specific questions are:

- 1) Whether Applicant abandoned the subject matter of the claims.
- 2) Whether the subject matter of claims 23-42 is to an invention so different from that of issued claims 1-2 so that a Reissue Patent would include 'different inventions.'
- 3) Whether Applicant is attempting to improperly "recapture" subject matter waived in the prosecution of the original application.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

### RELATED APPEALS AND INTERFERENCES

Appellant and counsel do not know of any other pending U.S. Patent Applications that are on appeal which have issues that overlap with the issues in this Appeal. No Interference proceedings before the U.S. Patent and Trademark Office are known by Appellants to have any substantive relationship to the subject matter of this Appeal.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

#### **GROUPING OF CLAIMS**

The following grouping of claims is made in compliance with the requirements of 37 C.F.R. 1.191 for the content of an Appeal Brief. The following grouping of claims is made to expedite this Appeal and narrow issues, and is not intended to waive or limit the right of the Applicants to enforce and defend claims separately, even though they are grouped for convenience in this Appeal.

Claims 23, 24, 27 and 28 shall stand or fall with the patentability of Claim 23 for all issues considered in this Appeal.

Claims 25, 26 and 29 shall stand or fall with the patentability of claim 25 for the purposes of this Appeal. Claim 25 differentiates itself from claim 23 by recitation of specific bacteria that are enhanced in the process.

Claims 31-42 shall stand or fall together with the patentability of claim 31 for the purposes of this Appeal. Claim 31 further differentiates itself from claim 25 by not only reciting the specific class of bacteria used in the enhancement process, but also by limiting the process to an *in vitro* or cell culture host of bacteria or virus, and subsequently collecting by-products generated from that growth.

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

#### ARGUMENTS OF APPELLANT

#### **SUMMARY OF THE ARGUMENTS**

The basic issues raised in this Appeal revolve around the question of whether a Reissue Application allows Appellant to claim the subject matter recited in claims 23-42. The basic arguments against allowing the claims are not based upon any issue of Novelty under 35 USC 102 or Obviousness under 35 USC 103. All arguments relate to technical issues unique to Reissue Practice. Those issues may be summarized as follows, with Appellant's position stated thereafter.

1. The Patent was granted for a specific invention, and the Reissue claims are to not only a different invention, but to the opposite invention.

The allowed claims are for the suppression of growth of specific bacteria. The claims on Appeal include claims towards the enhancement of microorganism growth. It has been asserted, without true consideration of the prosecution history, that the inventions are therefore clearly opposite and different and cannot be allowed in the same patent.

The Title of U.S. Patent No. 5,629,349 is "COMPOUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS." The title of the issued Patent is consistent with the original claims in the first four applications that recited the modulation of growth of organisms. The original intended scope of the invention was a truly generic invention of modulating the growth of microorganisms. That truly generic disclosure and the truly generic claims originally filed in the applications are generic to both the claims allowed in U.S. Patent No. 5,629,349 and the claims presently on Appeal. Just as claims to altering the volume of an audio device would include increasing and decreasing the volume, modulating clearly includes and was disclosed as including enhancing growth and suppressing growth. The **inventions are not opposite**, but they are intimately related.

The rejection of record is clearly in error for asserting that the issued claims and the claims on Appeal are unrelated and to different inventions. That assertion fails to consider the

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

actual disclosure, the original claims, and the technical relationship between the subject matter. The rejection as different inventions is therefore clearly in error.

# 2. The rejection asserts that Applicant abandoned the subject matter of the claims on Appeal.

The rejection and the record have failed to appreciate the fact that a broadening Reissue Application allows Applicants to claim subject matter narrower in scope than the subject matter abandoned during the prosecution of the original patent. That issue, though repeatedly raised, has never been the subject of a response on the issue by the U.S. Patent and Trademark Office. The reason there has been no response is that every claim on Appeal is narrower in scope than any claim cancelled during prosecution of the last application, where that claim encompassed the subject matter of the claims in this Appeal. The claims on this Appeal are therefore in strict compliance with the regulations and provisions of broadening reissue practice.

The rejection is clearly in error and must be withdrawn. Applicant may be held to have abandoned an invention broader than the claims on Appeal, but the narrower claims on Appeal are consistent with the broadening Reissue practice of the U.S. Patent and Trademark Office.

# 3. Applicant never intended to claim the subject matter on Appeal in the prosecution of U.S. Patent No. 5,629,349.

Appellant cannot comprehend the basis for this assertion. The title, the disclosure and the original claims in every application in the series of application included claims to the modulation of growth. This is pointed out in detail below. It was because of error and mistake in the prosecution of the Patent that inadequate protection of the actual invention of the specification and original claims was not achieved.

Any reading of the claims originally filed in the application that issued as U.S. Patent No. 5,629,349 will show an intent to claim an invention generic to both enhancement and

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

suppression of bacterial growth and viral growth. Evidence was actually introduced in the form of a letter from the inventor to prior counsel showing a lack of comprehension on why the scope of the claims was being diminished. This evidence was submitted at the specific request of the Examiner. In spite of this clear record, the rejection remains that Appellant never intended to claim subject matter generic to the subject matter of the claims on Appeal. This assertion is clearly in error, and this will be shown in detail in the discussions and arguments below.

### DETAILED ARGUMENTS OF APPELLANT

The rejections and issues in the Application are as follows:

# FACTOR I. Abandonment of Claimed Subject Matter Based on the Instant File History

- A) It is asserted the file history shows that Applicant Lyte "...had <u>ABANDONED</u> any inventions pertaining to the enhanced growth of bacteria and harvesting by-products based on the file history of Application Ser. No. 08/266,805...The first action in this Application was a restriction submitted on March 01, 1995 as noted below:..."
- B) The Examiner then points out that at the time of the restriction requirement, only claims 24 and 25 and claims 26-28 were present in the application. Both of these sets of claims are drawn towards suppressing the growth of gram positive or gram negative organisms.
- C) The Examiner also notes that the final rejection was based upon issues solely relating to formal issues under 35 U.S.C. 112, first and second paragraphs.
- D) Based on this record, the Office Action mailed March 24, 2000 asserts that "...(D)uring prosecution of the claims under consideration at that time including generic claims were abandoned due to the rejections by the Examiner.
- E) It is asserted that "No restrictions were submitted based on the generic claim that was found not to be allowable. Applicant Lyte had effectively abandoned the generic claim in view of the claims submitted in Serial No. 08/266,805."

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

- F) From September 13,1992 to may 12, 1997, Applicant Lyte had the opportunity prior to the issue of the patent to submit claims covering "the important invention of enhancing the growth of bacteria and viruses and harvesting by-products of the bacterial and virus."
- G) Applicant is offered the opportunity to submit evidence on the record that he did not abandon the claimed subject matter by presenting certified copies of the alleged 'clear instructions and explanations that I gave the attorney."
- H) Although the following issues do not relate clearly to the subject issue of the abandonment of the invention, the Examiner also asserts in this grouping of issues that "...the issue of the claimed subject matter to a different invention based on the record involves a lack of diligence on the part of Applicant to submit an application to the different and patentably distinct subject matter and he abandonment of the claimed subject matter which subject matter was not present in the original patented application for the alleged generic claim." (Emphasis natural).
- I) Applicant is asserted to not be within the guidelines of Section 251 that there was an error within the meaning of "recapture rule" based on the history and the patented claims under consideration....Applicant's failure to timely file another application to the claimed subject matter is not considered to be an error causing a patent granted on examined claims to be partially inoperative by claiming less than the applicant had a right to claim. Thus applicant's error is not correctable by reissue of the original patent under 35 U.S.C. 251.

## FACTOR 2 Reissue Applications - DIFFERENT INVENTIONS

A) The new claims 23-42 are "drawn to an invention which is not considered to conform to the same general invention as the original patent. That is, claims 23-42 are drawn to patentably distinct inventions....Claims 1-2 are drawn to a method of suppressing the growth of...bacteria..." (Claims 3-11 [now claims 23-31] which inventions are <u>directly opposite</u> to claims 23-32 which are drawn to "<u>enhancing the growth of bacteria</u>..."

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

B) In addition it was asserted that there was no search and examination of any aspect to any methods of enhancing the growth of bacteria. As enhancing the growth cannot conform to the issued claims of suppressing the growth of bacteria, the present claims do not conform to the subject matter of the general invention elected and allowed in the original application.

C) These patentably distinct inventions (claims 23-42) "would have been restricted" along with the other inventions as set forth in the restriction election in the Office action of 31 January 1995, had they been presented at that time. Accordingly, claims 23-42 stand withdrawn from further consideration on the merits.

# <u>FACTOR 3</u> - LACK OF INTENT TO CLAIM THE SPECIES NOW CLAIMED IN THE REISSUE

It is asserted that claims 23-42 are rejected under Section 251 as containing claims to different inventions that were not submitted in the original patent, U.S. 5,629,349. The Office Action then cites the MPEP and case law to the effect that:

- A) In situations where a reissue applicant presents claims for the first time that are distinct and separate from the claims of the patent, the examiner must follow the practice resulting from <u>In re Amos</u>, 953 F.2d 613 [and not offer a restriction requirement].
- B) A reissue applicant's failure to file a divisional application is not considered to be error causing a patent granted on elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. [citing three cases, at least one of which was previously cited by applicant].
- C) Likewise, if the original patent specification shows an intent not to claim the newly presented invention, that invention cannot be added by reissue. "If the reissue application presents claims to species not claimed in the original patent, election of species should not be required, but the added claims may be rejected, where appropriate, for lack of defect in the original patent and lack of error in obtaining the original patent as discussed above."

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

## PRELIMINARY REMARKS CONCERNING THE REISSUE APPLICATION

Applicants have addressed all of the specific issues and grounds of rejection below. Applicant for Reissue would also like to thoroughly explore the letter by Applicant for Reissue that was sent to the Senior partner of the law firm handling the original patent and it parent applications. That letter provides clear and convincing evidence that the Applicant for Reissue never intended to abandon the subject matter originally claimed and that he gave advice about the inadequacy of the support given by the law firm and identified that the cited art was inadequate to sustain any continued rejection of the claims for "...a direct action..on bacterial growth..." (Emphasizing the generic concept and not the limited concept of altering the rate of growth, not merely suppressing growth). The letter is analyzed in detail below.

Dr. Mark Lyte (the sole inventor on the Application) wrote to Mr. Orrin M. Haugen on February 14, 1994 discussing the prosecution of the Application. The following quotations are of import:

- a) "How the Examiner still believes that these references contemplate my discovery solely on the basis that references 'call for the introduction of catecholamines into the host medium' is beyond scientific (or rational) logic"
- b) "The methods and tools one would use to practice the two arts would be based on totally different methodologies and approaches..."
- c) The use of my invention which calls for a <u>direct</u> action of the catecholamines on bacterial growth states a direct methodology for the control of bacterial growth which can be practiced as a distinct art from what the other references claim...This point has been recognized by every scientific body at which these results have been presented." (Emphasis natural)

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

d) In the past I have not been adequately consulted by either Deb Parrish or Tom Naber before they have filed final patent applications or responses to Actions. For example, I did not see the Request for Reconsideration S.N. 07/847,196 that Mr. Naber filed September 17, 1993..."

These quotations provided corroborated evidence that Dr. Lyte did not agree with the rejections of record (see a) and b) above), believed that his invention was still directed towards controlling (**not suppressing**) the growth of bacteria by the introduction of hormones (quotation c), above); and felt that he was not being consulted on responses and amendments taken by at least two counsel.

Given this background and corroborated evidence, the specific issues listed above can be better discussed and traversed.

# RESPONSE TO THE ISSUES RAISED IN THE FINAL ACTION I. The Patentability of Claims 23, 24, 27 and 28 shall stand or fall with the patentability of Claim 23 for all issues considered in this Appeal.

Applicant for Reissue will specifically address each issue and supporting argument made by the Office Action.

# FACTOR I. Abandonment of Claimed Subject Matter Based on the Instant File History

A) It is asserted the file history shows that Applicant Lyte "...had ABANDONED any inventions pertaining to the enhanced growth of bacteria and harvesting by-products based on the file history of Application Ser. No. 08/266,805...The first action in this Application was a restriction submitted on March 01, 1995 as noted below:..."

There was no restriction requirement on March 1, 1995. The record shows a restriction requirement on January 31, 1995 (Paper No. 18), and an election filed on February 7, 1995

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

(which was acknowledged in Paper No. 20, the Office Action mailed on March 23, 1995. More importantly, that restriction requirement was between two distinct groups of claims directed towards:

- 1) suppression of growth of gram-positive bacteria and
- 2) suppression of growth of gram negative bacteria.

That restriction requirement cannot be the basis for asserting abandonment of enhancing the growth of bacteria. Those claims remaining at this stage of prosecution were directed solely towards suppression of growth. No intent can be read into the response to a restriction requirement between species **that did not include enhanced growth** to assert that enhanced growth was abandoned. Additionally, the claims remaining at that stage of prosecution, without any restriction requirement having been made between suppression and enhancement, are claims chosen by counsel for his strategic purposes and do not represent abandonment.

There was an earlier effective election held, but those claims (where present as claims 24-33) restricted out as "constructively elected" (without citation of authority) were directed towards a method of diagnosing bacterial growth and a method for producing glucose. None of those claims are generic to or a species of the concept of enhancing the growth of bacteria. That earlier "constructive election" (which is believed to be improper) cannot form a substantive basis for this holding of abandonment either.

Furthermore, as the Applicant was not being properly informed of decisions made by counsel, <u>Applicant cannot be held to have abandoned inventions that were never restricted out of the application</u>.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of abandonment based upon this issue must be withdrawn.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

# B) The Examiner then points out that at the time of the restriction requirement, only claims 24 and 25 and claims 26-28 were present in the application. Both of these sets of claims are drawn towards suppressing the growth of gram positive or gram negative organisms.

In effect, in this recognition of the only actual restriction requirement made in the history of the Application, the Examiner has acknowledged the impossibility of asserting that Applicant abandoned subject matter **not included in the restriction**. The only holding that could be made in this instance is that applicant abandoned (by failing to file a divisional/continuation application) the suppression of growth of gram-negative bacteria with claims of equal scope as those canceled following the restriction and election of March 23, 1995 between the two sets of claims, claims 24-25 and claims 26-28.

The record cited by the Office Action cannot support abandonment of the enhancement of bacterial/viral growth by the election as that species of the invention was not present in the claims that were restricted.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of abandonment based upon this issue must be withdrawn.

# C) The Examiner also notes that the final rejection was based upon issues solely relating to formal issues under 35 U.S.C. 112, first and second paragraphs.

The Examiner apparently is asserting that as claims were canceled/withdrawn after the rejection, those claims not continued in prosecution were abandoned. In making this recognition of the only actual rejection made at this point in the history of the Application, the Examiner has acknowledged the impossibility of asserting that Applicant abandoned subject matter **not** included in the rejection. The only holding that could be made in this instance is that applicant abandoned (by failing to file a divisional/continuation application) the suppression of growth of gram-negative bacteria with claims of equal scope as those canceled following the rejection of

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

claims for formal reasons (issues of claim structure and scope under 35 U.S.C. 112) between the two sets of claims, claims 24-25 and claims 26-28.

The record cited by the Office Action cannot support abandonment of the enhancement of bacterial/viral growth by the responses filed to that Office Action as neither that genus or that species of the invention was present in the claims that were rejected.

D) Based on this record, the Office Action mailed March 24, 2000 asserts that "...(D)uring prosecution of the claims under consideration at that time including generic claims were abandoned due to the rejections by the Examiner.

As has been shown above, claims directed towards the enhanced growth of bacteria and viruses were not present in the application when either a rejection or restriction requirement was made, and that Applicant was not being consulted on final decisions made by counsel. The record cited by the Office Action do not support the contention that claims generic to the enhanced growth of bacteria were either present when a substantive rejection was made or when a restriction requirement was made. In the absence of those events, it is impossible to assert a sustainable finding that "generic claims were abandoned."

The record cited by the Office Action cannot support abandonment of the enhancement of bacterial/viral growth by the election as that species of the invention was not present in the claims that were rejected under formal grounds under 35 U.S.C. 112.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of abandonment based upon this issue must be withdrawn.

E) It is asserted that "No restrictions were submitted based on the generic claim that was found not to be allowable. Applicant Lyte had effectively abandoned the generic claim in view of the claims submitted in Serial No. 08/266,805.

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

The original claims submitted in the Application Serial No. 08/266,805 still contained the generic claims (e.g., claim 1) for "affecting the growth of vectors and cell structures" that constituted a generic invention. That original claim was not the subject of a restriction requirement. In fact, contrary to the assertion of the Office Action, those claims were the subject matter of a substantive examination (note the Office Action mailed September 25, 1992), but were not subject to a restriction requirement.

Additionally, the rejected claims were far broader than the claims presently in this Reissue Application, and abandonment (if it occurred) for the broader claims does not constitute abandonment of the narrower claims submitted in this reissue. Applicant, Dr. Mark Lyte, did not abandon generic claims of the scope presented here in this Application. His letter to counsel subsequent to this Office Action establishes his ongoing belief in the fact that the references did not affect either the novelty or unobviosuness of his invention. He clearly indicated that the response filed prior to the date of his letter (in February of 1994) were being done without his final consultation and that he did not believe that he was being adequately represented.

The original claims contained generic language broader than that presently recited in the claims 23-42. Applicant has also provided written evidence contemporaneous with the prosecution of the application that he felt the invention being prosecuted was for "the control of bacterial growth" and not just suppressing growth. That is the language quoted from the letter of February 14, 1994.

The record cited by the Office Action cannot support abandonment of the enhancement of bacterial/viral growth by the rejection as that genus of the invention was not present specifically in the claims that were rejected under formal grounds under 35 U.S.C. 112 or prior art grounds under 35 U.S.C. 102 or 35 U.S.C. 103. Broader claims were rejected. It is for this reason that claims of a scope less then the generic claim rejected are being prosecuted now, as there was clear error and mistake by counsel in not filing claims of intermediate scope at that

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

time, and Applicant was under the uninformed (literally) belief that adequate claims to "control of bacterial growth" were being prosecuted.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of abandonment based upon this issue must be withdrawn.

F) From September 13, 1992 to May 12, 1997, Applicant Lyte had the opportunity prior to the issue of the patent to submit claims covering "the important invention of enhancing the growth of bacteria and viruses and harvesting by-products of the bacterial and virus."

As established in the letter, Applicant was not being informed of the final form of substantive amendments and response being made in the application. The letter only partially establishes the level of frustration and inadequate communication between the inventor and counsel. As noted by the letter, Applicant, Dr. Mark Lyte, was still arguing on the basis of limitations on "the control of bacterial growth" while those original limitations were not understood by him to be present in the application.

The Applicant did not have an informed opportunity prior to the issuance of the patent to submit the broader claims. That is the purpose of this Reissue Application. Claims broader than those presently sought were present in the original filing of the Application resulting in the Lyte Patent, and the limited claims allowed to issue were allowed to issue in error as far as the Applicant for Reissue is concerned. The evidence of record clearly supports this, and no legal barriers estopping the Applicant have been proven.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of abandonment based upon this issue must be withdrawn.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

G) Applicant is offered the opportunity to submit evidence on the record that he did not abandon the claimed subject matter by presenting certified copies of the alleged 'clear instructions and explanations that I gave the attorney."

Having first been given this opportunity in the Office Action mailed March 24, 2000, Applicant for Reissue, Dr. Mark Lyte, has submitted the letter dated February 14, 1994 to substantiate this position. It is believed that Applicant for Reissue has fully met his burden on this issue. The letter could not be much more clear on the issue of clear instructions, dissatisfaction with representation, and disbelief as to the rejection.

I) Applicant is asserted to not be within the guidelines of Section 251 that there was an error within the meaning of "recapture rule" based on the history and the patented claims under consideration....Applicant's failure to timely file another application to the claimed subject matter is not considered to be an error causing a patent granted on examined claims to be partially inoperative by claiming less than the applicant had a right to claim. Thus applicant's error is not correctable by reissue of the original patent under 35 U.S.C. 251.

It is the very nature of a broadening reissue, as defined and authorized by the Rules of Practice to provide claims that are broader than those allowed in the original Patent.

Specifically, the MPEP states that:

"No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." MPEP 1412.03

The MPEP continues with the commentary that:

"If the reissue application is timely filed within two years of the original patent grant and the applicant indicates in the oath or declaration that the claims will be broadened, then applicant may further broaden the claims in the pending reissue prosecution, even if the actual broadening occurs beyond the two year limit. [citing cases]"

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

It is absolutely clear that Reissue practice allows for the presenting of claims that are broader than claims allowed in the original patent, and narrower than those rejected in the prosecution of the original application. There are specific rules and case law that apply to the nature of breadth that is not allowed, but these events or situations are not present in the submitted claims, as has been outlined in detail in documents originally filed with the application and repeated, in part, herein. Those non-acceptable forms of broadening would include claims including non-elected subject matter and claims including a scope of an invention broader than or of the same scope that was canceled during the original prosecution of the Patent in order to obtain the claims of that Patent (Recapture Doctrine), and the factual basis for clearly identifying that the present claims do not fall within those exclusions has been thoroughly briefed in the earlier documents submitted at the time of filing. The Examiner is courteously requested to review the briefed issues in those documents.

Additionally, it is to be noted what the Recapture Rule specifically stands for. As noted in the M.P.E.P., section 1412.02 states that:

"The recapture rule bars the patentee from acquiring, through reissue claims that are of the *same* or *broader scope* than those claims that were canceled from the original application. On the other hand, the patentee is free to acquire, through reissue, claims that are narrower in scope than the canceled claims."

This is exactly the fact situation of the present Reissue Application. The scope of the original claims was for affecting the rate of growth of cells, while the present scope is for enhancing the rate of growth of bacteria, viruses, etc. The present claim structure is in fact specifically not included within the Recapture Rule. This issue is in error on both factual and legal grounds and must be withdrawn.

IT IS ABSOLUTELY CRITICAL TO NOTE THAT <u>EVERY SINGLE CLAIM PRESENT</u> <u>IN THIS REISSUE APPLICATION IS NARROWER IN SCOPE THEN THE</u>

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

# NARROWEST CLAIMS SUBMITTED AS CLAIMS 1-23 IN THE ORIGINAL APPLICATION

This fact is essential, as this fact overrides every single issue raised in the rejection of record. That is, as no claim was rejected or abandoned in the original Application that issued as the Patent, there can be no issue of recapture (as noted later), and no issue of abandonment, as all claims now in the Application are of intermediate scope of the claims allowed in the patent and the generic claims and all dependent claims to enhanced growth filed in the original application. This fact must be appreciated for a reasoned decision to be made in the present Reissue Application.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of abandonment based upon this issue must be withdrawn.

All issues raised under Factor I have been addressed and shown to be in error.

## FACTOR 2 Reissue Applications - DIFFERENT INVENTIONS

A) The new claims 23-42 are "drawn to an invention which is not considered to conform to the same general invention as the original patent. That is, claims 23-42 are drawn to patentably distinct inventions....Claims 1-2 are drawn to a method of suppressing the growth of...bacteria..." (Claims 3-11 [now claims 23-31] which inventions are directly opposite to claims 23-32 which are drawn to "enhancing the growth of bacteria..."

This assertion is based upon a narrow view of the Application. Patent and the prosecution history. The broadest claims for the invention were for "affecting the growth rate" of cells (and many other biological denominations). That was a true generic claim. Even though the original Patent was by mistake and without the intent of the Reissue Applicant, narrowed to suppression, the inventor was and still is under the correct belief that the invention is "affecting the growth

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

rate." This encompasses both the suppressions and enhancement of growth rates. The mere fact that the claims were erroneously and without consent of Reissue Applicant narrowed within the genus, does not make the two species opposite in the underlying nature of the invention. The two species, suppressing and enhancing were disclosed as part of a single genus (affecting the growth rate), and mere circumstance does not so fundamentally alter the underlying nature of the invention as to make them opposites, even if they mathematical vector expressed in their recitation may have opposite signs (i.e., + versus -). The species were disclosed and originally claimed as part of a genus.

Please note the portion of the response, below, dealing with issue C) that will further strengthen the original impression of the Patent and Trademark Office on this issue.

B) In addition it was asserted that there was no search and examination of any aspect to any methods of enhancing the growth of bacteria. As enhancing the growth cannot conform to the issued claims of suppressing the growth of bacteria, the present claims do not conform to the subject matter of the general invention elected and allowed in the original application.

This assertion is clearly in error. The original rejection against claims 1-23 in this Application that resulted in the patent, was a rejection under 35 U.S.C. 102/103 and 35 U.S.C. 112 against claims 1-23, claims that included the original generic language of "affecting the growth rate of vectors and cell cultures and living organisms."

It is to be noted, as emphasized above, that all claims in the present Reissue are intermediate in scope of the claims allowed in the patent and the claims originally filed in the Application, 08/266,805. Therefore, the search performed on the broader claims had to include the search of the narrower claims. This is further substantiated by the fact that certain of the references were directed towards enhancing the rate of growth (albeit for production rate of oocytes in clams). Therefore the Examiner fully appreciated the fact that the original claims covered enhancement of growth rates as well as suppression of growth rates.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

The search on that species was in fact done in the original claims, even though those claims were of much broader scope than the claims presently pending in the Reissue Application.

This issue is not supported by the record, and is found to lack factual and legal basis for the assertion. This assertion of different inventions based upon this issue must be withdrawn.

At least of equal importance, as will be emphasized directly below, there was no Restriction requirement among the species of suppression of growth and enhancing the growth rate of vectors, cells structures, and organisms as originally claimed. The generic claim was addressed as a true generic claim by the Patent and Trademark Office without restriction.

C) These patentably distinct inventions (claims 23-42) "would have been restricted" along with the other inventions as set forth in the restriction election in the Office action of 31 January 1995, had they been presented at that time. Accordingly, claims 23-42 stand withdrawn from further consideration on the merits.

This is not only pure supposition by the Patent and Trademark Office, given in hindsight, but is controverted by the fact that the Examiner did not require restriction when presented with the original generic claims encompassing both enhancement and suppression. The assertion by the Office Action is clearly in error as in the Office Action of September 25, a992, when the original true generic claim was present, there was no Restriction Requirement. All claims (claims 1023) were substantively addressed in the Office Action, under 35 U.S.C. 102/103 and 35 U.S.C. 112.

This issue is clearly in error in fact and must be withdrawn. All issues raised under **Factor II** have been addressed and traversed. No ground raised under this section can be substantively supported by facts or law, and should be withdrawn.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

# <u>FACTOR 3</u> - LACK OF INTENT TO CLAIM THE SPECIES NOW CLAIMED IN THE REISSUE

It was asserted that claims 23-42 are rejected under Section 251 as containing claims to different inventions that were not submitted in the original patent, U.S. 5,629,349. The Office Action then cites the MPEP and case law to the effect that:

A) In situations where a reissue applicant presents claims for the first time that are distinct and separate from the claims of the patent, the examiner must follow the practice resulting from In re Amos, 953 F.2d 613 [and not offer a restriction requirement].

As was noted above, broader claims than those presently in the Reissue Application were present in the Application that resulted in U.S. Patent No. 5,629,349. Original claims 1-23 were broader in scope then any claim remaining in the present application. Those claims were pending in 07/847,196 which was continued as U.S. patent Application 08/266,805. As the Supreme Court has held that a continuation application is in fact the same as the parent application, even though different time periods may apply, the Claims were by Case law present in this application. These claims were presented for the first time in their literal language, but are narrower in scope and of substantially the same content as the claims originally filed in this application.

That argument could not be made for the claims later added to monitoring or detecting changes in growth rate, as they were not within the scope of claims originally submitted. The present claims are in fact within the scope of claims submitted and they are not new inventions.

B) A reissue applicant's failure to file a divisional application is not considered to be error causing a patent granted on elected claims to be partially inoperative by reason of claiming

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

less than the applicant had a right to claim.[citing three cases, at least one of which was previously cited by applicant].

Applicant could have filed a continuation application, if he had been apprized of the legal capability, but he could not have filed a divisional on the claimed subject matter. As there was no restriction requirement vis-a-vis claims directed to the enhancement of the rate of growth, a divisional application could not have been filed. A divisional application, or one so designated, can be filed only as the result of a restriction requirement. As no such restriction requirement was made on the record of this Application, there was no possibility of filing a divisional application.

This is far more important than mere semantics. Applicant went to the extreme of briefing this specific point when filing the patent application. If there had, in fact, been a restriction requirement in this Application between the sub-generic species of suppression and enhancement (not the "constructive election" asserted as against the "detection of growth rate change" claims asserted in the January 31, 1994 Office Action), then there would be an issue to decide on this point. However, there was never such a restriction requirement in this Application for patent. The issue is without factual and legal foundation and must be withdrawn.

C) Likewise, if the original patent specification shows an intent not to claim the newly presented invention, that invention cannot be added by reissue. "If the reissue application presents claims to species not claimed in the original patent, election of species should not be required, but the added claims may be rejected, where appropriate, for lack of defect in the original patent and lack of error in obtaining the original patent as discussed above."

The original patent specification, and in fact the original claims as filed in this Application, show a clear intent to cover the species of enhanced growth rate. This basis for

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

asserting an issue is clearly in error. The original claims in the application were generic to both enhancement and suppression, the specification specifically mentioned enhancement as well as suppression, and the examples clearly supported enhancement as well as suppression. The absence of claims to that subject matter is due to clear error during prosecution of the Application to U.S. Patent No. 5,629,349. These claims are the proper venue for a Reissue Application for patent.

# II. The Patentability of Claims 25, 26 and 29 shall stand or fall with the patentability of claim 25 for the purposes of this Appeal. Claim 25 differentiates itself from claim 23 by recitation of specific bacteria that are enhanced in the process.

All of the arguments presented above with respect to the Patentability of claims 23-24, 27-28 and 30 are equally applicable to these claims. In addition, these claims are further limited, placing them even further within the realm of subject matter properly claimed in a Broadening Reissue Application.

As noted above, the issues involved in this Appeal relate to a comparison among 1) the scope of claims on Appeal, the scope of claims prosecuted and the scope of claims cancelled during prosecution of the original Patent, and the scope of claims allowed in the Patent.

With regard to the issue of "abandonment of invention," claims as narrow as or narrower than claims 25, 26 and 29 were never present within the original applications and claims present in those earlier applications were broader than each of these claims. It is therefore impossible to hold that these claims were abandoned. These claims clearly represent the precise fact situation and issues where a broadening Reissue Application is appropriate.

With regard to the issue of different invention, these claims again represent a scope of invention within the scope of generic claims previously filed in the series of applications ultimately resulting in U.S. Patent No. 5,629,349. The relationship among the original recitation in the applications of "altering" rate of growth and the term in the issued Patent of "suppressing"

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant: Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

as compared to the present language of "enhancing" is quite clear. Altering is generic to the positive vector of enhancing and the negative vector of suppressing. This is the same as reciting "moving" as a generic term to be inclusive of forward and rearward motion. Altering was described in the original applications as generic to both suppressing growth and to enhancing growth. These claims are clearly within the scope of claims that are within the scope of claims originally sought in the Patent and removed by error and mistake.

It was asserted that claims 23-42 are rejected under Section 251 as containing claims to different inventions that were not submitted in the original patent, U.S. 5,629,349. As clearly and repeatedly noted above, claims generic to the claims here presented were present in the original applications, including generic claims to the harvesting of materials from enhanced growth of cells and microorganisms. The present claims are clearly subgeneric to the claims originally and repeatedly present within the original application.

III. Claims 31-42 shall stand or fall together with the patentability of claim 31 for the purposes of this Appeal. Claim 31 further differentiates itself from claim 25 by not only reciting the specific class of bacteria used in the enhancement process, but also by limiting the process to an *in vitro* or cell culture host of bacteria or virus, and subsequently collecting by-products generated from that growth.

All of the arguments presented above with respect to the Patentability of claims 23-24, 27-28 and 30 are equally applicable to these claims. In addition, these claims are further limited, placing them even further within the realm of subject matter properly claimed in a Broadening Reissue Application.

With regard to the issue of "abandonment of invention," claims as narrow as or narrower than claims 25, 26 and 29 were never present within the original applications and claims present in those earlier applications were broader than each of these claims. It is therefore impossible to

United States Patent and Trademark Office Attorney Docket No. 933.001USR

Applicant :Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

hold that these claims were abandoned. These claims clearly represent the precise fact situation and issues where a broadening Reissue Application is appropriate.

With regard to the issue of different invention, these claims again represent a scope of invention within the scope of generic claims previously filed in the series of applications ultimately resulting in U.S. Patent No. 5,629,349. The relationship among the original recitation in the applications of "altering" rate of growth and the term in the issued Patent of "suppressing" as compared to the present language of "enhancing" is quite clear. Altering is generic to the positive vector of enhancing and the negative vector of suppressing. This is the same as reciting "moving" as a generic term to be inclusive of forward and rearward motion. Altering was described in the original applications as generic to both suppressing growth and to enhancing growth. These claims are clearly within the scope of claims that are within the scope of claims originally sought in the Patent and removed by error and mistake.

It was asserted that claims 23-42 are rejected under Section 251 as containing claims to different inventions that were not submitted in the original patent, U.S. 5,629,349. As clearly and repeatedly noted above, claims generic to the claims here presented were present in the original applications, including generic claims to the harvesting of materials from enhanced growth of cells and microorganisms. The present claims are clearly subgeneric to the claims originally and repeatedly present within the original application.

## **SUMMARY OF THIS APPEAL**

Each and every issue raised in the Office Action has been fully addressed and traversed in this Brief On Appeal. The Examiner and the Board of Appeal are earnestly requested to review the content of the "DECLARATION FOR BROADENING REISSUE APPLICATION" filed with the original Reissue Application. That declaration more thoroughly discusses the issues raised in this Office Action and Briefs the issues with respect to the law and Patent Rules. Applicant incorporates those comments herein, rather than merely repeating them.

United States Patent and Trademark Office

Attorney Docket No. 933.001USR

Applicant : Mark Lyte Serial No.: 09/241,825 Filed: February 1, 1999

Title: COMPUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

#### CONCLUSION

All rejections of record have been shown in detail to be in error. The rejection should be reversed and all claims should be indicated as allowable.

Applicants believe the claims are in condition for allowance and request reconsideration of the application and allowance of the claims. The Examiner is invited to telephone the below-signed attorney at 952.832.9090 to discuss any questions that may remain with respect to the present application.

Respectfully submitted,

MARK LYTE

By their Representatives,

MARK A. LITMAN & ASSOCIATES, P.A. York Business Center, Suite 205 Edina, MN 55435

(952)832.9090

Date 3) August 2000

Name

Reg. No. 26,390

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to

Box AF, Assistant Commissioner of Patents, Washington, D.C. 20231 on August \_\_\_\_\_\_, 2000.

MARK A. LITMAN

Signature (